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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/534,081	06/13/2005	Kohji Fukatsu	3119 USOP	8962
21874	7590	12/26/2008	EXAMINER	
EDWARDS ANGELL PALMER & DODGE LLP			CORNET, JEAN P	
P.O. BOX 55874			ART UNIT	
BOSTON, MA 02205			PAPER NUMBER	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/534,081	Applicant(s) FUKATSU ET AL.	
	Examiner JEAN CORNET	Art Unit 4121	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-38 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

This application is a 371 of PCT/JP03/14139 filed on 11/06/2003 which claims priority to the foreign application 2002-324632 filed on 11/08/2002.

Claims 1-38 are pending.

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-9, drawn to a compound by the formula (I') and (I)

If this group is elected a single disclosed species of compound is also required. Further restriction based on the election may be made.

Group II, claim(s) 10-12, & 34 drawn to a compound by the formula (I -1)

If this group is elected a single disclosed species of compound is also required. Further restriction based on the election may be made

Group III, claims 13-15, 22, 23 & 34 drawn to a compound by the formula (I-2)

If this group is elected a single disclosed species of compound is also required. Further restriction based on the election may be made

Group IV, claims 16-21, drawn to a compound by the formula (I-2A)

If this group is elected a single disclosed species of compound is also required. Further restriction based on the election may be made

Group V, claims 24-27, drawn to a compound by the formula (I-3)

If this group is elected a single disclosed species of compound is also required. Further restriction based on the election may be made

Group VI, claims 28-31, & 34 drawn to a compound by the formula (I-4).

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If this group is elected a single disclosed species of compound is also required. Further restriction based on the election may be made

Group VII, claims 32-33, drawn to a compound by the formula (I-4A).

If this group is elected a single disclosed species of compound is also required. Further restriction based on the election may be made

Group VIII, claims 35, drawn to a method regulating a GPR40 receptor function.

If this group is elected a single disclosed species of compound is also required. Further restriction based on the election may be made

Group IX, claim 36, drawn to a method of using a compound having an aromatic ring and a group capable of releasing a cation for the production of a GPR40.

If this group is elected a single disclosed species of compound is also required. Further restriction based on the election may be made

Group X, claim 37, drawn to a method for screening a ligand, agonist or antagonist to GPR40.

If this group is elected a single disclosed species of compound is also required. Further restriction based on the election may be made

Group XI, claim 38, drawn to a kit for screening a ligand, agonist or antagonist to GPR40.

If this group is elected a single disclosed species of compound is also required. Further restriction based on the election may be made

It is noted that claim 36 is a use claim.

2. The inventions listed as Groups I, II, III, IV, V, VI, VII, VIII, IX, X and XI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

3. An international application should relate to only one invention or, if there is more than one invention, the inclusion of those inventions in one international application is only permitted if all inventions are so linked as to form a single general inventive

concept (PCT Rule 13.1). With respect to a group of inventions claimed in an international application, unity of invention exists only when there is a technical relationship among the claimed inventions involving one or more of the same or corresponding special technical features.

4. The expression “special technical feature” is defined in PCT Rule 13.2 as meaning those technical features that define a contribution which each of the inventions, considered as a whole, makes over the prior art. The determination is made on the contents of the claims as interpreted in light of the formulas. Whether or not any particular feature makes a “contribution” over the prior art and therefore constitutes “a special technical feature” should be considered with respect to novelty and inventive step.

5. The common technical feature in all groups is that the compound represented by formula (I). This element can not be a special technical feature under PCT Rule 13.2 because the element is shown in the prior art.

In this case, the international application (**WO97/31907**) **description page 2 paragraph 5 and the abstract** supplied in the IDS discloses that the compound having formula I, which has the same core structure as the compound of formula I disclosed in the instant application and is used in treatment and prophylaxis of hyperglycemia, non-insulin dependent diabetes mellitus (NIDDM) or Type II diabetes. As a result no technical feature exists among the different groups because the inventions of Groups I, II, III, IV, V, VI, VII, VIII, XI, X and XI fail to make a contribution over the prior art with

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respect to novelty and inventive step. In conclusion, there is a lack of unity of inventions and therefore restriction for examination purpose as indicated is proper.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP

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§ 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Election of Species

7. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

Specific aromatic ring and a group capable of releasing cation

Specific substituents/groups on the compounds for all the formulas (a species for example is methyl, NOT alkyl);

8. Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. Specifically;

As to claims 1-9, Applicant is required to define a specific compound with an aromatic ring and a group capable of releasing cation for the formula (I') and (I).

As to claims 10, 12 & 34, Applicant is required to define a specific compound for the formula (I-1)

As to claims 13, 15, 22, 23 & 34, Applicant is required to define a specific compound for the formula (I-2)

As to claims 16, 17, 20 & 21, Applicant is required to define a specific compound for the formula (I-2A)

As to claims 24-27, Applicant is required to define a specific compound for the formula (I-3)

As to claims 28-30, 31 & 34, Applicant is required to define a specific compound for the formula (I-4)

As to claims 32 & 33 Applicant is required to define a specific compound for the formula (i-4A)

As to claims 35-38, Applicant is required to define a compound having an aromatic ring and a group capable of releasing cation.

Upon Applicant's election of species, the result must provide a single chemical species. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The following claim(s) are generic:

claims 1 & 2 as to Group I; claims 10 as to Group II; claim 13 as to Group III;
and claim 16 as to Group IV; claim 24 as to Group V; claim 28 as to Group VI; claim 32
as to Group VII; claims 35-38 as to Group VIII, IX, X and VI.

9. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

each chemical species is a distinct chemical which lacks a special technical feature in view of international application (WO97/31907) description page 2 paragraph 5 and the abstract supplied in the IDS alternatively, use: the fact that each chemical species contains a distinct moiety such that each chemical species is of a dissimilar nature.

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing**

the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JEAN CORNET whose telephone number is (571)270-7669. The examiner can normally be reached on Monday-Friday 7.30am-5.00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patrick Nolan can be reached on 571-272-0847. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JC

/Patrick J. Nolan/
Supervisory Patent Examiner, Art Unit 4121